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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,285	09/25/2003	Pancras C. Wong	PH 7494 NP	7284

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EXAMINER
HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,285	WONG ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/21/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-20 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statement filed November 21, 2003 has been received and entered into the application. As reflected by the attached, completed form PTO-1449 (1 page), the cited references have been considered.

Claim Objection

Claim 1 is objected to because of the following informality:

At line 1, "method method" should be changed to ---method---. Appropriate correction is required.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al. (WO 98/57951, cited by applicants) in view of Bernat et al. (U.S. Patent No. 5,989,578).

Lam et al. teach the pyrazole-containing compound identified as "Compound A" in present claim 1 as well as pharmaceutically acceptable salts thereof (see page 5, lines 7-13 and page 21, the compound at lines 53-55) as being useful as anticoagulants for the treatment or prevention of thromboembolic disorders in mammals (page 225, lines 1-3). Lam et al further teaches that a composition containing such compound can be combined with one or more additional therapeutic agents which include other anticoagulant or coagulation inhibitory agents, anti-platelet or platelet inhibitory agents, thrombin inhibitors, thrombolytic agents or fibrinolytic agents. At page 228, line 25, aspirin is highlighted as such an additional therapeutic agent. At page 232, lines 1-7, it is taught that conventional pharmaceutical diluents, excipients etc. may be employed in a composition which contains the active agents. Each of the drugs administered may be administered at the same time or sequentially in any order at different points in time. (page 228, lines 6-11). As to the dosage amounts of the active ingredients to be used, Lam et al. teach that where two or more active agents are administered, generally the amount of each component may be reduced relative to the usual dosage, i.e., sub-therapeutic, of the agent when administered alone, in view of the additive or synergistic effect of the therapeutic agents when administered in combination (page 235, lines 31-37).

Respecting the thromboembolic disorders that may be treated, Lam et al. highlight arterial or venous cardiovascular or cerebrovascular thromboembolic disorders, including, for example, unstable angina, first or recurrent myocardial infarction, ischemic sudden death, transient ischemic attack, stroke, atherosclerosis, venous thrombosis, deep vein thrombosis,

thrombophlebitis, arterial embolism, coronary and cerebral arterial thrombosis, cerebral embolism, kidney embolisms and pulmonary embolisms.

The differences between the above and the claimed subject matter lie in that Lam et al. fail to highlight:

(1) clopidogrel or a pharmaceutically acceptable salt thereof, anti-arrythmic agents or cholesterol lowering agents, such as pravastatin, as an additional therapeutic agent; and

(2) each of the thromboembolic disorders as in present claim 12.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(1) Lam et al., as set forth above, teach that anti-platelet or platelet inhibitory agents may additionally be employed and Bernat et al. teach clopidogrel as being such an agent (col. 1, lines 5-8). The skilled artisan would have been motivated to employ clopidogrel because Lam et al. teach ticlopidine as a preferred anti-platelet agent (page 228, lines 30-34) while Bernat et al. teach that clopidogrel is superior to ticlopidine as an anti-platelet agent (col. 2, lines 34-47). The skilled artisan would have been motivated to employ an anti-arrythmic agent or a cholesterol lowering agent, such as the well know drug pravastatin, because heart arrythmias and/or high cholesterol levels were well recognized to be associated with or else a risk/causative factor in a variety of the thromboembolic disorders taught by Lam et al.

(2) Lam et al. teach arterial or venous cardiovascular or cerebrovascular thromboembolic disorders in general and the determination of any specific type disorder to treat from those known to the skilled artisan would have been well within the artisan's purview.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J. Henley III
Primary Examiner
Art Unit 1614

Mar. 2, 2004